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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/935,151	08/22/2001	Gregory Alan Steube	20518/13 (S-8475)	9252
7590	04/07/2005			EXAMINER
Mark S. Leonardo, Esq. Brown Rudnick Freed & Gesmer One Financial Center Box IP, 18th Floor Boston, MA 02111			WILLIAMS, CATHERINE SERKE	
			ART UNIT	PAPER NUMBER
			3763	
DATE MAILED: 04/07/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/935,151	STEUBE, GREGORY ALAN	
<b>Examiner</b>		<b>Art Unit</b>	
Catherine S. Williams		3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 26 August 2004.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-26 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
 Paper No(s)/Mail Date \_\_\_\_\_
- 4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date. \_\_\_\_\_
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/26/04 has been entered.

### ***Response to Amendment***

The amendment filed 8/26/04 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: **non-sealing fin.**

Applicant is required to cancel the new matter in the reply to this Office Action.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-19 and 21-26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the

claimed invention. Specifically, the specification does not provide a description of how the fin is **non-sealing**.

### *Claim Objections*

Claims 17, 24 and 25 are objected to because of the following informalities:

Claim 17 recites in line 2 “the needle cannula” which should read --a needle cannula-- since claim 5 did not introduce a needle cannula and this is the first presentation of the limitation.

Claim 24 recites in line 1 “a needle support” which was already introduced in claim 21.

The recitation in claim 24 should be changed to –the needle support--.

Claim 25 recites in line 1 “a needle cavity” which was already introduced in claim 21.

The recitation in claim 24 should be changed to –the needle cavity--.

Appropriate correction is required.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

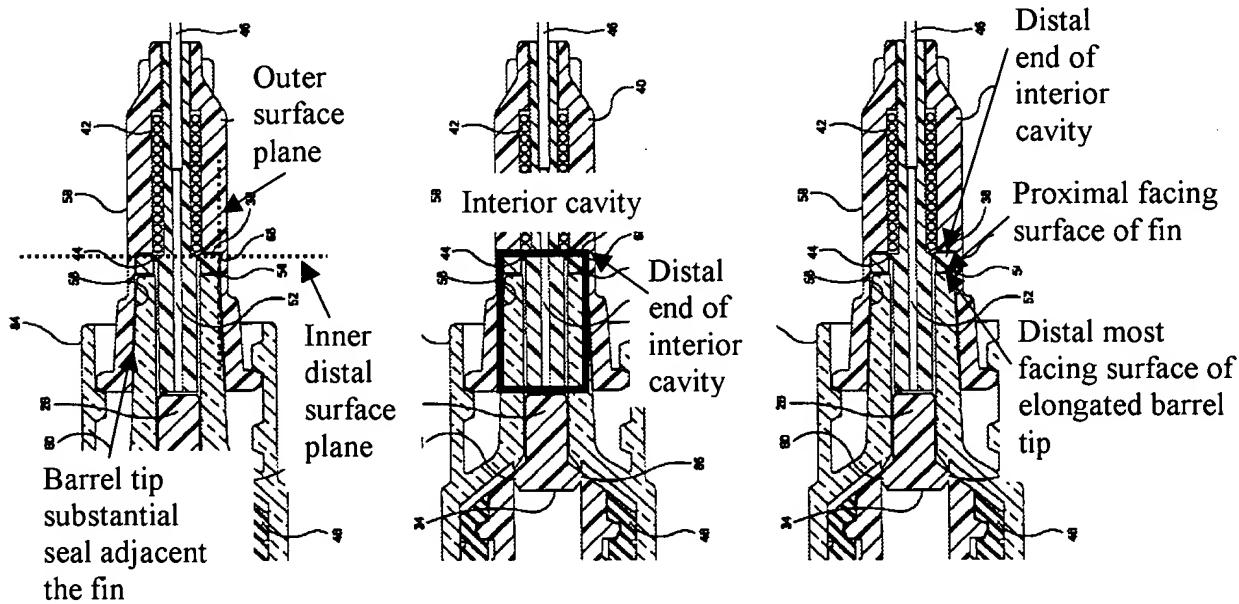
A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7,10-18 and 21-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Carter et al (USPN 6,010,486). Regarding claims 1,5 and 21, Carter discloses a needle assembly that includes a needle hub (40) defining an interior cavity (see middle figure below), a distal end (see middle figure below), and one non-sealing rigid fin (54) having an outer surface plane that intersects an interior surface plane of the needle hub (see left figure below) that defines the

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interior cavity. The fin is considered rigid because the cross hatching for the fin used in figure 6 indicate that the material used is plastic. In order for any type of plastic material to maintain the shape of the fin shown in figure 6, the property of the plastic material used would necessarily have to include some degree of rigidity. The fin is considered non-sealing in that the prior art specification does not reference the element (54) as a gasket, o-ring or seal. The fin extends longitudinally a fixed distance from the distal end of the interior cavity to a proximal facing surface (see right figure below). The proximal facing surface engages a distal most facing surface of an elongated barrel tip (see right figure below). The needle hub also includes a needle support (tubular portion of 38 not including fin) which extends through the interior cavity. A barrel (20) has a proximal end and a distal end with the barrel tip at the distal end which is received within the interior cavity. See figure 2 and middle figure below.



Regarding claims 2-4 and 22, the barrel tip is elongated and extends from the distal end of the barrel (see figures above). The interior cavity has an annular configuration, see figure 2 in conjunction with figure 6. The barrel tip forms a substantial seal adjacent the fin in that the outer

surface of the barrel tip is fastened to the interior surface (56) of the needle hub (40). See above figures. Additionally, even though the prior art does not specify that the fastening of the needle hub to the barrel tip forms a seal, the claim language only recites a substantial seal and to seal is defined as “to close or make secure against access, leakage, or passage by a fastening or coating” (see <http://www.merriam-webster.com/cgi-bin/dictionary>). In this case, the connection of the needle hub (40) to the barrel tip closes off access to the barrel tip by the fastening or connection of the two elements and thereby reads on the limitation of a “substantial seal”.

Regarding claim 6-7, the barrel tip forms a substantial seal with the needle support (38) adjacent the fin when the barrel tip receives the needle support after use and the barrel tip closes against access to the used needle support via the fastening or connection of the barrel tip with the spring of the needle support (see definition above). Since the barrel tip closes the needle support against access after use, the closing reads on the limitation of “a substantial seal with”. See figure 7.

Regarding claims 10-17 and 23-26, the needle hub (40) includes a hub skirt (see flange on proximal end of needle hub (4) in figure 6). The interior cavity (see above middle figure) is annularly defined between the perimeter of the hub skirt and the interior axis of the needle support (38). The needle support (38) has a needle cavity (52) having a portion of the needle disposed therein. See figure 6. As shown in figure 6, the needle cavity and interior cavity are coaxial. Since the cavities are coaxial, they are also substantially parallel since they extend in the same longitudinal direction. As shown in figures 6-7, the barrel receives a plunger (30) that is configured to engage a proximal opening of the needle support (38).

Regarding claim 18, it is assumed that applicant is invoking 112 6<sup>th</sup> paragraph and means plus function interpretation. Therefore, the claim limitation has been reviewed in light of the

structure disclosed in the instant specification for achieving/performing the claimed function. Upon review of the specification, the means for engaging was determined to include the structure of at least one fin. As described above the prior art device includes a barrel (30) with a barrel tip and a non-sealing rigid fin. Additionally, the configuration shown in figure 6 is such that minimal space occurs between the needle hub components in which extra medicament fluid can collect. Hence, the configuration of the needle hub structure, including the fin, minimizes medicament fluid waste.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 8-9 and 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carter. Carter meets the claim limitations as described above but fails to include four fins.

However, at the time of the invention, it would have been an obvious design choice by one skilled in the art to make the one fin of Carter into four separate fins. Applicant has not disclosed that having four fins instead of one provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Carter's needle hub, and applicant's invention, to perform equally well with either one fin as taught by Carter or the claimed four fins.

Additionally, one skilled in the art would recognize in the device of Carter that the frangible point (44) between the needle support (38) and the fin (54) is severed during use of the device. See figures 6-7. One skilled in the art would recognize that the force required to sever a solid annular frangible portion is greater than the force required to sever four smaller frangible portions. Hence, the motivation for making the fin of Carter into four smaller fins would have been an obvious design choice in order to solve a recognizable problem by one skilled in the art to decrease the amount of force needed to use the device of Carter.

***Response to Arguments***

Applicant's arguments with respect to claims 1-26 have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine S. Williams whose telephone number is 571-272-4970. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas D. Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*Catherine S. Williams*

Catherine S. Williams

April 1, 2005